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Premarket Notification (510(k)) Summary

510(k) Number: K052791

Product Name: AMPHIRION™ DEEP 0.014" OTW PTA Balloon Catheter

Common Name: Peripheral Transluminal Angioplasty Catheter

Class: Class II, 21 CFR Sec 870.1250, Product Code DQY

Submitter's Name:
ev3 Inc.
4600 Nathan Lane North
Plymouth, MN 55442

Official Contact:
Stephanie K. Isgrigg Robinson
Regulatory Affairs Specialist
Telephone: 763-398-7036

Summary Preparation Date: September 30, 2005

This summary is provided in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission for a modification to the AMPHIRION™ DEEP 0.014" OTW PTA Balloon Catheter

The AMPHIRION™ DEEP 0.014" OTW PTA Balloon Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The AMPHIRION DEEP catheter is a coaxial lumen device with a semi-compliant balloon. The lumen marked "WIRE" is the central lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire with a maximum outer diameter of 0.014". The lumen marked "BALLOON" is the balloon inflation lumen, which is used to inflate and deflate the dilatation balloon. The catheter tapers beneath the balloon segment to achieve the lowest possible deflated profile. Two radiopaque marker bands are placed under the balloon segment of the catheter shaft to provide visual reference points for balloon positioning within the vessel. The distal catheter shaft is hydrophilic coated.

The modified device is substantially equivalent* to the currently marketed PTA balloon catheter in intended use, materials, technological characteristics and performance. Performance testing (bench) further supports a substantial equivalence claim. The collective evidence therefore provides assurance that the AMPHIRION™ DEEP 0.014" OTW PTA Balloon Catheter meets the requirements that are considered acceptable for the intended use.

*This document uses the term "substantial equivalence" as intended in 21 CFR 807.87, and not as defined in Title 35 of the US Code.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2005

ev3 Inc.
c/o Ms. Stephanie K. Isgrigg Robinson
Regulatory Affairs Specialist
4600 Nathan Lane North
Plymouth, MN 55442

Re: K052791
Trade Name: AMPHIRION DEEP PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 30, 2005
Received: October 03, 2005

Dear Ms. Isgrigg Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: K052791

AMPHIRION DEEP™ Peripheral Transluminal Angioplasty (PTA) Balloon Catheter

Indications for Use:

The AMPHIRION™ DEEP 0.014" OTW PTA Balloon Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vuchnen

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052791